

IN THE CLAIMS

The status of each claim is listed below:

Claims 1-36: (Canceled).

37. (New): A process of lyophilization for the preparation of a piroxicam: β -cyclodextrin inclusion compound in a 1:2.5 molar ratio conducted on a kilogram scale, comprising:

- (a) dissolving piroxicam and β -cyclodextrin in the molar ratio of 1 to 2.5 and ammonium hydroxide in water brought to a temperature of at least 60 °C;
- (b) pouring the piroxicam and β -cyclodextrin dissolved in water from (a) on temperature-controlled shelves of a freeze-dryer pre-cooled to a temperature of at least -30 °C to lower the temperature of the solution to -10 °C at a cooling rate equal to or higher than 1 °C/min, to produce a frozen solution;
- (c) further lowering the temperature of the frozen solution to at least -20 °C; and
- (d) drying the frozen solution under vacuum,

wherein the inclusion reaction is complete with complete amorphization of the inclusion compound and complete conversion of the piroxicam to the zwitter-ionic form.

38. (New): The process of Claim 37, wherein the cooling rate is 1.5 °C/min.

39. (New): The process of Claim 37, wherein the shelves of the freeze-dryer are pre-cooled to a temperature of at least -40 °C.

40. (New): The process of Claim 37, wherein the temperature is lowered to between -30 and -40 °C.

41. (New): The process of Claim 37, wherein the water brought to a temperature of at least 60 °C from (a) is poured in a dewar filled with liquid nitrogen.

42. (New): The process of Claim 41, wherein the product obtained is in the form of solid granules.

43. (New): The process of Claim 37, wherein (d) is carried out at a temperature of 50-60 °C.

44. (New): The process of Claim 37, wherein the water in (a) is brought to a temperature of at least 70 °C.

45. (New): The process of Claim 44, wherein the water is brought to a temperature between 70 and 75 °C.

46. (New): The process of Claim 37, wherein the ammonium hydroxide is used in a concentration of 28-30 % and in a 1:1 ratio (w/w) with respect to piroxicam.

47. (New): The process of Claim 37, wherein the temperature of complete freezing of the hot solution is achieved in not more than 90 minutes.

48. (New): The process of Claim 37, which is conducted on an industrial scale.